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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,722	09/08/2000	Pramod K. Srivastava	8449-115-999	8697
20583	7590	03/08/2004	EXAMINER	
JONES DAY			YAEN, CHRISTOPHER H	
222 EAST 41ST STREET			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

1642

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,722

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,22-31 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,22-31, and 52-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 11/20/2003 is acknowledged and entered into the record. Accordingly, claims 1-18, 20-21, and 32-51 are canceled without prejudice or disclaimer.

2. Claims 19,22-31, and 52-55 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claims 19, 22-31, and 52-55 under 35 USC 112, 1st paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that the instant invention is claimed as a product-by-process and that such claims are proper in view of case law cited. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Because the population of the peptides recovered during each round of purification would be different and distinct, and because the tumor cells from which the population of peptides has not been disclosed, one of skill in the art would not be able to determine which of the thousand if not millions of peptides extracted from the claimed process are recovered. Further, the structure of such peptides cannot be adequately determined or defined because peptides derived from said tumors would be peptide fragments of unknown lengths and sequences. In MPEP § 2113, it is stated that "[i]f the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In

the instant case, the whole or partial structure of the peptide recovered using the claimed method cannot be determined, because no identifying characteristics have been taught and one of skill in the art would not be able to determine whether the recovered product is already within the public domain. Applicant's reliance on *In re Luck* is misplaced, because the method must define a structure in whole or in part, of which neither is the case in the instant invention. No identifiable characteristics or identifiable means of determining the structure have been set forth. Therefore, because the exact nature or structure of the peptide claimed cannot be determined by the skilled artisan, and because the process by which the product claimed does not define a definitive population of peptides either in whole or in part, one of skill in the art would not be able to determine that the applicant was in possession of the invention at the time the invention was made.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claim 19 under 35 USC 102 (b) as being anticipated by Berliner *et al* is maintained for the reasons of record. Applicant argues that the rejection is improper because the reference fails to teach each and every limitation of the claimed invention. Furthermore, applicant argues that the composition must comprise "a complex and a heterogeneous mixture of peptides". Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claim is drawn to a composition comprising a population of peptides produced by a specific process. The claims does not limit the population recovered to a

heterogeneous population of peptides nor does the claim limit the invention to a population of complexes. Encompassed within the scope of the claim is a single peptide mixture with a pharmaceutical carrier, such as the tyrosinase which is disclosed by Berlinier *et al.* The reliance on Noessner *et al* was to demonstrate that tyrosinases are associate with HSP-70.

Therefore, because the claims are not so limited as to preclude homogeneous mixtures (i.e. a mixture of a single protein) and a pharmaceutical carrier, and because tyrosinases have been isolated and shown to complex to HSP-70, the claim is anticipated.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

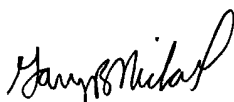
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
March 2, 2004


GARY NICKOL
PRIMARY EXAMINER